To: Ellen.Hart@fda.hhs.gov[Ellen.Hart@fda.hhs.gov]; Kelly.Hugunin@fda.hhs.gov[Kelly.Hugunin@fda.hhs.gov]; Angela.Clarke@fda.hhs.gov[Angela.Clarke@fda.hhs.gov]
Cc: Niman, Aaron[niman.aaron@epa.gov]; Nguyen, James[Nguyen.James@epa.gov]; Miller, David[Miller.DavidJ@epa.gov]
From: Rossmeisl, Colleen[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6B18311C740A4535907E690ACA5F5924-ROSSMEISL,]
Sent: Thur 9/30/2021 10:25:16 PM (UTC)
Subject: RE: Upcoming meeting with EPA/FDA on Seresto
Results of Elanco Data Analysis 2016-2020_Draft interagency deliberative.docx
FDA Technical Discussion - Seresto Incident Analysis_Draft Interagency deliberative.pptx

Interagency Deliberative, material not for release outside of the federal government

Hi all –

As mentioned in the email sent earlier this week, we are providing some additional material in preparation for the meeting next week.

2 documents are attached:

1. Slides for next week's meeting
2. Initial draft data analysis results

We will discuss each of these further at the meeting, but wanted to provide them in advance for your review. If you have any questions about the material ahead of the meeting, please feel free to reach out to us. We may also provide some of the incident data early next week, but still trying to determine the best way to transmit this material (was recommended to send as an encrypted email, but that does not seem to be working outside the agency). As noted above, please treat these materials as interagency deliberative, not for release outside of the federal government.

Looking forward to our discussion on the 6th!

Thanks –
Colleen

From: Rossmeisl, Colleen
Sent: Tuesday, September 28, 2021 8:50 AM
To: Ellen.Hart@fda.hhs.gov; Kelly.Hugunin@fda.hhs.gov; Angela.Clarke@fda.hhs.gov
Cc: Niman, Aaron <niman.aaron@epa.gov>; Nguyen, James <Nguyen.James@epa.gov>; Miller, David <Miller.DavidJ@epa.gov>
Subject: Upcoming meeting with EPA/FDA on Seresto

Hi Ellen, Kelly and Angela –

It was nice meeting you at our first meeting and we look forward to our October 6th technical meeting to continue our discussion on Seresto.

We plan to share an agenda and additional background documents in advance of the meeting and will aim to provide these materials no later than this Friday. Attached please find some older presentation slides that were part of a 2016 meeting between FDA and EPA on data analysis of EPA-regulated flea and tick control products. Our discussion next week will be more focused on our current analysis of Seresto, but we thought it would be helpful to share because our analytical approach will likely be similar and be subject to similar limitations/considerations.

Although we will discuss this more at the meeting, I wonder if you have any material/information you might be able to share on FDA's methodology for adverse event causality assessments. We are considering several methodologies (e.g., ABON, WHO-UMC, etc.) and wanted to consider the methodology used by FDA as well. I have found some general information on factors considered by FDA (which are similar to others), but was looking for more specific criteria if they are available.

Thanks for any feedback!
Colleen

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